



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0712; FRL-9915-47]

Sulfentrazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of sulfentrazone in or on apple.

The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0712, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0712 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0712, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 30, 2013 (78 FR 79359) (FRL-9903-69), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E8202) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.498 be amended by establishing tolerances for residues of the herbicide sulfentrazone, (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide), and its metabolite HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, calculated as the stoichiometric equivalent of sulfentrazone, in or on apple at 0.15 parts per million (ppm). That document referenced a summary of the petition prepared on behalf of IR-4 by FMC Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has determined that it is appropriate to establish the tolerance in or on apple for the combined residues of the free and conjugated forms of the herbicide sulfentrazone, and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, calculated as the stoichiometric equivalent of sulfentrazone. The reason for this decision is discussed in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sulfentrazone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sulfentrazone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Subchronic and chronic toxicity studies in rats, mice, and dogs identified the hematopoietic system as the target of sulfentrazone. Sulfentrazone inhibits the enzyme protoporphyrinogen oxidase (PPO) in target plants, and the results of subchronic and chronic toxicity studies in mammalian systems are consistent with PPO inhibition. Disruption of heme biosynthesis was indicated by signs of anemia, and decreases in hematocrit (Hct), hemoglobin (HGB), and mean corpuscular volume (MCV) in mice, rats, and dogs at comparable dose levels from short- through long-term exposures without a significant increase in severity.

Sulfentrazone caused developmental effects when administered via the oral (rats and rabbits) and dermal (rat only) routes of exposure. Developmental effects in rats and rabbits consisted of reductions in the number of implantations in rats, and increases in early resorptions and reduction in live fetuses per litter in rats and rabbits. Surviving rat fetuses exhibited reduced/delayed skeletal ossifications, and decreased fetal body weights. Developmental effects in rats were seen in the absence of maternal toxicity. In contrast with the rat studies, developmental effects in rabbits were observed at a maternally toxic dose, where clinical signs of toxicity included hematuria (red blood cells in urine), abortions, and decreased body-weight gains. In the 2-generation reproductive toxicity study in rats, developmental effects included an increased duration of gestation, reduced prenatal viability (fetal and litter), reduced litter size, and an increased number of stillborn pups. Pup body-weight deficits, along with reduced pup and litter postnatal survival, were also observed. All of the offspring effects were reported in the presence of mild maternal toxicity (decreased body weight and body-weight gain, particularly in F₁ females). No systemic toxicity was seen via the dermal route up to the limit dose in a 28-day dermal toxicity study in adult non-pregnant rabbits. In a dermal developmental study in rats, there was an increased quantitative fetal susceptibility. While no maternal effects were observed up to the highest dose tested, fetal effects were observed at this dose, and consisted of decreased body weights, increased incidences of fetal variations, hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, incompletely ossified ischia or pubis, and a reduced number of thoracic vertebral and rib ossification sites.

In the 26-day inhalation toxicity study, effects that were considered treatment related and adverse effects occurred only at the highest concentration tested. Systemic effects at this concentration consisted of significant reductions in red blood cell (RBC) parameters including RBC count, HGB concentrations, Hct, MCV, mean corpuscular HGB (MCH), and/or reticulocytes

in both sexes. Portal-of-entry effects in this study consisted of an increased incidence of minimal nasal respiratory epithelial hyperplasia in both sexes as well as minimal laryngeal epithelial attenuation in all test material exposure groups. The effects on hematological parameters were reversible after 28 days of recovery, while the nasal injury persisted.

In an acute neurotoxicity (ACN) study in rats, effects consisted of an increased incidence of clinical signs of toxicity (staggered gait, splayed hind limbs, and abdominal gripping), changes in functional-observation battery (FOB) parameters, and decreased motor activity at a high dose level. Complete recovery was observed by day 14, and there was no evidence of neuropathology. In a rat subchronic neurotoxicity (SCN) study, clinical signs of toxicity, increased motor activity, and/or decreased body weights, body-weight gain, and food consumption were also observed with no evidence of neuropathology. A published, non-guideline developmental toxicity study in the rat did not conclusively demonstrate developmental neurotoxicity and contained several shortcomings that limit its use for regulatory purposes, including the lack of a no-observed-adverse-effect-level (NOAEL) (DeCastro VL, Destefani CR, Diniz C, Poli P., 2007, *Evaluation of neurodevelopmental effects on rats exposed prenatally to sulfentrazone*. Neurotoxicology 28(6):1249-59). The reported effects involving measures of physical and reflex development are likely secondary effects reflective of the poor general state of the offspring as reported in the rat 2-generation reproductive toxicity study at similar dose levels but with a well-defined NOAEL.

In the 28-day rat immunotoxicity study, there were no effects on the immune system and systemic effects consisted of reduced body weight, and increased absolute and relative spleen weights at the highest dose tested. Carcinogenicity studies in rats and mice showed no evidence of increased incidence of tumor formation due to treatment with sulfentrazone, and the EPA has classified sulfentrazone as not likely to be carcinogenic to humans. The available

mutagenicity studies indicate that sulfentrazone is weakly clastogenic in the *in vitro* mouse lymphoma assay in the absence of S9 activation. There is no evidence that sulfentrazone is mutagenic in bacterial cells or clastogenic in male or female mice *in vivo*.

Specific information on the studies received and the nature of the adverse effects caused by sulfentrazone as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “Sulfentrazone – Preliminary Human-Health Risk Assessment for Registration Review and the Risk Assessment for the Section 3 Registration Request for a New Use on Apples” at pp. 44-49 in docket ID number EPA-HQ-OPP-2013-0712.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for sulfentrazone used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Sulfentrazone for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-49 years of age)	NOAEL = 14 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.14 mg/kg/day aPAD = 0.14 mg/kg/day	2-generation Reproductive Toxicity Study - Rat Offspring Toxicity LOAEL = 33 (M) and 40 (F) mg/kg/day based on reduced prenatal viability (fetal & litter), reduced litter size, increased number of stillborn pups, reduced pup and litter postnatal survival, and decreased pup body weights throughout lactation
Acute dietary (General population including infants and children)	NOAEL = 250 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 2.5 mg/kg/day aPAD = 2.5 mg/kg/day	Acute Neurotoxicity (ACN) Study - Rat LOAEL = 750 mg/kg/day based on increased incidence of clinical signs and FOB parameters and decreased motor activity
Chronic dietary (All populations)	NOAEL = 14 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.14 mg/kg/day cPAD = 0.14 mg/kg/day	2-generation Reproductive Toxicity Study - Rat Offspring Toxicity LOAEL = 33 (M) and 40 (F) mg/kg/day based on reduced prenatal viability (fetal & litter), reduced litter size, increased number of stillborn pups, reduced pup and litter postnatal survival, and decreased pup body weights throughout lactation
Incidental oral short- (1 to 30 days) and intermediate-term (1- 6 months)	NOAEL = 14 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	2-Generation Reproductive Toxicity Study - Rat Offspring LOAEL = 33 mg/kg/day based on decreased pup body weights and reduced postnatal survival in both generations
Dermal short-term (1 to 30 days)	Dermal study NOAEL = 100 mg/kg/day UF _A = 10 x UF _H = 10 x FQPA SF = 1x	LOC for MOE = 100	Dermal Developmental Study - Rat LOAEL = 250 mg/kg/day based on decreased fetal body weight; increased incidences of fetal skeletal variations: hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, and incompletely ossified ischia or pubes; and reduced number of thoracic vertebral and rib ossification sites

Short-term (1-30 days) inhalation	Portal-of-entry NOAEL = 0.256 mg/L, HEC = 0.054 mg/L, HED = 1.55 mg/kg/day $UF_A = 3x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 30	Portal-of-entry LOAEL = 1.71 mg/L based on an increased incidence of minimal nasal respiratory epithelial hyperplasia in male and female rats.
Cancer (Oral, dermal, inhalation)	Sulfentrazone is classified as not likely to be carcinogenic to humans		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). HEC = human-equivalent concentration. HED = human-equivalent dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sulfentrazone, EPA considered exposure under the petitioned-for tolerances as well as all existing sulfentrazone tolerances in 40 CFR 180.498. EPA assessed dietary exposures from sulfentrazone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for sulfentrazone, and EPA performed separate acute risk assessments for females 13 to 49 years old and for the general population, including infants and children, based on different endpoints and acute population adjusted doses (aPADs). In estimating acute dietary exposures, EPA used the Dietary Exposure Evaluation Model, Food Consumption Intake Database (DEEM-FCID, ver. 3.16), which incorporates consumption data from United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003-2008). As to residue levels in food, EPA assumed tolerance-level residues, 100 percent crop treated (PCT), and DEEM (ver. 7.81) default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used DEEM-FCID, ver. 3.16, which incorporated consumption data from the USDA's NHANES/WWEIA; 2003-2008. As to residue levels in food, EPA assumed tolerance-level residues, 100 PCT, and DEEM (ver. 7.81) default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that sulfentrazone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for sulfentrazone. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for sulfentrazone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of sulfentrazone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of sulfentrazone for acute exposures are estimated to be 37.3 parts per billion (ppb) for surface water and 134 ppb for ground water; and for chronic exposures for non-cancer assessments are estimated to be 5.3 ppb for surface water and 98 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 134

ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 98 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Sulfentrazone is currently registered for the following uses that could result in residential exposures: Residential home lawns/turf and recreational turf, such as golf courses. EPA assessed residential exposures using the following assumptions: Adults were assessed for potential short-term dermal and inhalation handler exposures from applying sulfentrazone to residential turf/home lawns and for short-term postapplication dermal exposure from contact with treated residential and recreational turf.

Children, ages 11 < 16 years old and 6 < 11 years old, were assessed for postapplication dermal exposure from contact with treated residential and recreational turf (home lawns and golf courses). Children, ages 1 < 2 years old, were assessed for postapplication short-term dermal and incidental oral exposures (hand-to-mouth, object-to-mouth, and episodic ingestion of granules), as well as short- and intermediate-term incidental oral soil ingestion scenarios from contact with residential turf/home lawns.

The recommended adult residential exposure scenario for use in the aggregate assessment reflects short-term dermal exposure from applications to turf via backpack sprayer. The recommended residential exposure scenario for use in the combined short- and intermediate-term aggregate assessment for children ages 1 < 2 years old reflects dermal and hand-to-mouth exposures from postapplication exposure to turf applications. This combination should be considered a protective estimate of children's exposure to pesticides used on turf since the incidental oral scenarios are considered inter-related, likely occurring interspersed

amongst each other across time; therefore, combining these scenarios would be overly-conservative because of the conservative nature of each individual assessment. In addition, the only potential intermediate-term exposure is postapplication soil ingestion which is significantly less than short-term hand-to-mouth exposure. Further, this scenario is considered protective of potential post-application exposures to children, ages $6 < 11$ and $11 < 16$ years old, as children 1-2 years old represent the population subgroup for children with the greatest exposure, and is therefore considered protective of other children population subgroups.

Chronic exposures are not expected and were not assessed. Finally, residential handler and/or postapplication inhalation risk estimates were not combined with dermal or oral risk estimates in the aggregate risk assessment since the toxicological effects in the inhalation toxicological study were portal-of-entry and were different from those seen in the dermal and oral toxicological studies. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found sulfentrazone to share a common mechanism of toxicity with any other substances, and sulfentrazone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sulfentrazone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a

common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is evidence of increased quantitative susceptibility following *in utero* exposure in the oral and dermal rat developmental toxicity studies. Developmental effects, including decreased fetal body weights and reduced/delayed skeletal ossifications, were observed at doses that were not maternally toxic. In the 2-generation reproduction study in rats, offspring effects such as decreased body weights and decreased litter survival were observed at a slightly maternally toxic dose (slightly decreased body weight gain), indicating possible slightly increased qualitative susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for sulfentrazone is complete.

ii. In the ACN and SCN studies, observed effects included changes in motor activity and FOB parameters, clinical signs, and body-weight decrements. There is low concern for neurotoxicity since:

1. Effects were seen at relatively high doses;
2. Effects occurred in the absence of neuropathology;
3. There is no evidence of neurotoxicity in other available studies in the toxicity database;
4. Effects are well-characterized with clearly established NOAEL/LOAEL values; and
5. The selected PODs are protective of these effects.

iii. There was evidence for increased quantitative susceptibility following oral and dermal exposures in the developmental toxicity studies in rats. Although developmental toxicity was observed at lower doses than maternal toxicity in both studies in the rat, the concern is low based on the following considerations:

1. The toxicology database for assessing pre- and postnatal susceptibility is complete;
2. There are clear NOAELs and LOAELs for the developmental effects observed via both the oral and dermal routes;
3. The PODs used for assessing dietary and dermal exposure risks are based on developmental and/or offspring toxicity;
4. The portal-of-entry effects seen in the 26-day inhalation study are protective of the developmental toxicity; and
5. There are no residual uncertainties for pre-and/or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to sulfentrazone in drinking water. EPA used similarly conservative

assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by sulfentrazone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to sulfentrazone will occupy 6.7% of the aPAD for females 13-49 years old, and 1.1% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure for all populations other than females 13-49 years old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sulfentrazone from food and water will utilize 7.1% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of sulfentrazone is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Sulfentrazone is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to sulfentrazone.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 480 for adults. Because EPA's level of concern for sulfentrazone is a MOE of 100 or below, this MOE is not of concern.

4. *Short- and intermediate-term risk.* Combined short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Sulfentrazone is currently registered for uses that could result in short- and intermediate-term residential exposures, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to sulfentrazone.

Using the exposure assumptions described in this unit for combined short- and intermediate-term exposures, EPA has concluded that the combined short- and intermediate-term food, water, and residential exposures result in an aggregate MOE of 260 for children 1-2 years old, the population subgroup for children with the greatest exposure. Because EPA's level of concern for sulfentrazone is a MOE of 100 or below, this MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, chemical name is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to sulfentrazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, gas chromatography (GC), is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for sulfentrazone.

C. Response to Comments

EPA received one comment to the Notice of Filing that made a general objection to the presence of any sulfentrazone residues on apple or any other crop. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework. The Agency has concluded after this assessment, that there is a reasonable certainty that no harm will result from aggregate human exposure to sulfentrazone.

D. Revisions to Petitioned-For Tolerances

EPA was petitioned to establish a tolerance in or on apple for residues of sulfentrazone and its metabolite HMS; however, upon review of the data supporting the petition, the Agency has determined that the apple tolerance should be established on the combined residues of the free and conjugated forms of sulfentrazone, including its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, calculated as the stoichiometric equivalent of sulfentrazone. EPA previously reviewed metabolism data and determined that the residues of concern are the parent compound, sulfentrazone, and the metabolites HMS and DMS (free and conjugated) in all crops except soybean seed, where the residues of concern are sulfentrazone and the metabolite HMS. Samples of raw agricultural and processed commodities from the apple studies were analyzed for residues of sulfentrazone and its metabolites DMS and HMS, and EPA is establishing an apple tolerance based upon those analyses.

V. Conclusion

Therefore, tolerances are established for residues of sulfentrazone, (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide), and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, calculated as the stoichiometric equivalent of sulfentrazone, in or on apple at 0.15 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 4, 2014.

Lois Rossi,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.498, add alphabetically the following commodity to the table in paragraph (a)(2) to read as follows:

§ 180.498 Sulfentrazone; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
Apple	0.15
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